



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/577,408 | 04/25/2006 | Francesco Cilurzo | 207,565 | 1408 |

7590 06/02/2011
Jay S. Cinamon
Abelman, Frayne & Schwab
666 Third Avenue
10th Floor
New York, NY 10017

| |
|----------|
| EXAMINER |
|----------|

SUTTON, DARRYL C

| | |
|----------|--------------|
| ART UNIT | PAPER NUMBER |
|----------|--------------|

1612

| | |
|-----------|---------------|
| MAIL DATE | DELIVERY MODE |
|-----------|---------------|

06/02/2011

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | |
|------------------------------|--------------------------------------|---------------------------------------|
| Office Action Summary | Application No. 10/577,408 | Applicant(s) CILURZO ET AL. |
| | Examiner DARRYL C. SUTTON | Art Unit 1612 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 April 2011.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 and 16-26 is/are pending in the application.
- 4a) Of the above claim(s) 6-11, 18-20, 25 and 26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 12-14, 16, 17 and 21-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| <p>1) <input type="checkbox"/> Notice of References Cited (PTO-892)</p> <p>2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)</p> <p>3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.</p> | <p>4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.</p> <p>5) <input type="checkbox"/> Notice of Informal Patent Application</p> <p>6) <input type="checkbox"/> Other: _____.</p> |
|---|--|

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 04/21/2011 has been entered. No new claims have been added.

Applicant's arguments filed 04/21/2011 have been fully considered. Rejections and/or objections not reiterated from previous Office Actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set of rejections and/or objections presently being applied to the instant application.

Claim Rejections - 35 USC § 103

(1) Claims 1, 4, 5, 12, 13, 16 and 17 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Barkalow et al. (US 2004/0096559) in view of Chen et al. (US 2003/0068378).

Applicant argues that the purpose of Barkalow et al. do not pertain to the same field of endeavor as the claimed invention and thus it is non-analogous art. The Examiner acknowledges that Barkalow et al. do not involve any pharmaceutical agent.

Art Unit: 1612

None of the Examples are in the field of the pharmaceutical field. Although Barkalow et al. mention edible films, in said films, however there is no distinction made among the possible film formers, so that an exceedingly large number of hydrocolloids are expressly taught as preferred.

The Examiner disagrees.

A prior art reference is evaluated for all that it reasonably suggests and is not limited to preferred embodiments and/or working examples. The Examiner has not been able to locate the alleged acknowledgement that Barkalow et al. do not involve pharmaceuticals. As a matter of fact, the Examiner cites the disclosure of Barkalow et al., "The product includes medicaments such as pharmaceutical agents [0027]" on page 4 of the Office action dated 10/22/2010. Barkalow et al. clearly teach that maltodextrin is a starch hydrolyzed product that can be used **alone** as a film former of the edible thin film [0024] and [0087] (emphasis added). One skilled in the art would reasonably expect that the edible films of Barkalow et al. could be manufactured with maltodextrin as the film forming agent. Accordingly, Barkalow et al. is analogous art, since the claimed invention is also drawn to a self-supporting film comprised of maltodextrin. The intended use of the films bear no patentable weight upon the examination of the film compositions.

Applicant argues that Chen et al. improperly includes maltodextrins among hydrocolloids and is therefore unreliable prior art. Chen et al. discloses 5-99% hydrocolloid. Chen et al. teaches away from the claimed invention. If Chen et al. was

Art Unit: 1612

modified to exclude hydrocolloids, the modification would render said dosage unit unsatisfactory and inoperable for their intended purpose. Chen et al. is non-analogous art since the dosage form is designed include hydrocolloids to adhere to the mucosal surface and then disintegrate and dissolve over a time frame, which is an effort that is distinct, unrelated and totally opposite in direction as the present invention.

The Examiner disagrees.

While the Examiner agrees that the inclusion of maltodextrin as a hydrocolloid in the disclosure of Chen et al. seems to be misplaced, the Examiner is interpreting maltodextrin's inclusion as a useful film forming agent as an admission by Chen et al. that, at the least, maltodextrin can be used as an equivalent to the hydrocolloids in the production of the edible films of Chen et al. Its inclusion would not lead the skilled artisan away from using maltodextrin as the film former and in the amounts disclosed by Chen et al. Further, Chen et al. is provided as prior art in this rejection in order to disclose antiemetic pharmaceutical agents that are incorporated into edible films which can be comprised of maltodextrin, and not for any specific film forming composition. Accordingly, Chen et al. provides adequate motivation for combining with the edible films of Barkalow et al. which are disclosed as having the ability to deliver pharmaceutical actives. The instant claims are drawn to a self-supporting film and the intended purpose of the film is given patentable weight.

Art Unit: 1612

(2) Claims 2 and 3 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Barkalow et al. and Chen et al. as applied to claims 1, 4, 5, 12, 13, 16 and 17 above, and further in view of Zyck et al. (US 2003/005039).

Applicant argues that claim 1 is entirely unobvious over the cited art, and the rejections of independent claims 2 and 3 have also been overcome.

The Examiner disagrees.

The Examiner's response to Applicant's arguments concerning Barkalow et al. and Chen et al. is provided *supra*. Accordingly, Zyck et al. is only required to provide motivation for combining with Barkalow et al. and Chen et al. Since Zyck et al. disclose that maltodextrin with a DE of less than 20 are used as film forming agents for edible films, it provides adequate motivation for combining.

(3) Claim 14 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Barkalow et al. and Chen et al. as applied to claims 1, 4, 5, 12, 13, 16 and 17 above, and further in view of Falkenhausen et al. (WO 2002/02085), US 2004/0028732 provided as a translation guide.

Applicant argues that claim 1 is entirely unobvious over the cited art, and the rejections of independent claims 2 and 3 have also been overcome.

The Examiner disagrees.

The Examiner's response to Applicant's arguments concerning Barkalow et al. and Chen et al. is provided *supra*. Accordingly, Falkenhausen et al. is only required to provide motivation for combining with Barkalow et al. and Chen et al. Since

Art Unit: 1612

Falkenhausen et al. disclose sheet-like disintegratable dosage forms, i.e. edible films, comprised of the antiemetic ondansetron and methods for preparing the edible films, it provides adequate motivation for combining.

(4) Claims 21-24 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Barkalow et al., Chen et al. and Falkenhausen et al. as applied to claim 14 above, and further in view of Kasper et al. (US 4,222,973).

Applicant has not provided an argument for this rejection, the Examiner is interpreting Applicant's argument that since claim 14 is not obvious over the cited art, to mean that claims 21-24 which are dependent on claim 14 are also overcome.

The Examiner disagrees.

The Examiner's response to Applicant's arguments concerning Barkalow et al., Chen et al. and Falkenhausen et al, is provided *supra*. Accordingly Kasper et al. is only required to provide motivation for combining with Barkalow et al., Chen et al. and Falkenhausen et al. Since Kasper et al. disclose that release papers, such as silicon, are used for casting films to allow the film to be easily removed from the paper after casting, it provides adequate motivation for combining.

(5) Claims 1, 4, 5, 12, 13, 16 and 17 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Chen et al. (US 2003/0068378)

Applicant's arguments concerning Chen et al. are provided *supra*.

The Examiner disagrees.

The Examiner's response to Applicant's arguments is provided *supra*.

(6) Claims 2 and 3 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Chen et al. as applied to claim 1, 4, 5, 12, 13, 16 and 17 above, and further in view of Zyck et al. (US 2003/0054039)

Applicant's arguments concerning Chen et al. and Zyck et al. are provided *supra*.

The Examiner disagrees.

The Examiner's response to Applicant's arguments is provided *supra*.

(7) Claim 14 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Chen et al. as applied to claim 1, 4, 5, 12, 13, 16 and 17 above, and further in view of Falkenhausen et al. (WO 2002/02085).

Applicant's arguments concerning Chen et al. and Falkenhausen et al. are provided *supra*.

The Examiner disagrees.

The Examiner's response to Applicant's arguments is provided *supra*.

No claims are allowed.

Conclusion

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic

Art Unit: 1612

Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darryl C. Sutton whose telephone number is (571)270-3286. The examiner can normally be reached on M-Th from 7:30AM to 5:00PM EST or on Fr from 7:30AM to 4:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass, can be reached at (571)272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/Darryl C Sutton/
Examiner, Art Unit 1612

/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612